

# Early cannulation of percutaneously created arteriovenous hemodialysis fistulae

Alexandros Mallios<sup>1</sup> , Gerald A Beathard<sup>2</sup>   
and William C Jennings<sup>3</sup> 

The Journal of Vascular Access  
2020, Vol. 21(6) 997–1002  
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DOI: 10.1177/1129729819892796  
journals.sagepub.com/home/jva



## Abstract

**Introduction:** The optimal vascular access for most dialysis patients is an arteriovenous fistula and the recognized appropriate process of care for the chronic kidney disease patient is to have the access in place ready for use when renal replacement therapy is required. Unfortunately, as a result of multiple barriers, most patients start dialysis with a catheter and many experience multiple interventions. The recent advent of the percutaneous arteriovenous fistula may offer at least a partial solution to these problems. The purpose of this study was to report of the results of early cannulation of the percutaneous arteriovenous fistula.

**Materials and Methods:** Early cannulation, less than 14 days post creation, was performed in 14 cases in order to avoid an initial catheter or continued use of a problematic catheter for dialysis. Immediately post access creation, blood flow ranged from 491 to 1169 mL/min (mean = 790 mL/min). Ultrasound was used to map potential cannulation sites prior to use. Cannulation was performed using plastic fistula cannulas.

**Results:** Early cannulation was successful in this cohort of cases except for one cannulation complication. Dialysis treatments were otherwise uncomplicated. Primary patency at 3, 6, and 12 months was 76%, 76%, and 66%, respectively. Assisted primary patency for the same intervals was 100%, 100%, and 91%, respectively. Cumulative patency was 100% at all three-time intervals.

**Conclusion:** The results of this study suggest that the possibility of successful early cannulation with a percutaneous arteriovenous fistula can be considered as an additional factor in making this access a reasonable alternative for a surgically created arteriovenous fistula in appropriate patients.

## Keywords

Arteriovenous fistula, early cannulation, percutaneous, ultrasound, plastic needle cannulation

Date received: 5 March 2019; accepted: 11 November 2019

## Introduction

The primary clinical goal of vascular access planning and creation for the chronic kidney disease (CKD) patient is to have the appropriate functional access in place ready for sustained clinical use at the initiation of dialysis. Secondary goals are to minimize patient morbidity from the primary and ancillary procedures that are required to achieve this goal. The optimal vascular access is an arteriovenous fistula (AVF) because of its lower morbidity and mortality, hospitalization rate, and cost.<sup>1–6</sup> Unfortunately, there are barriers to achieving these goals with the standard surgically created AVF. There are delays in scheduling surgical procedures for access creation and the time required for the AVF to mature. This can amount to several months.<sup>7,8</sup>

The problem is compounded by the fact that predicting the time for initiation of dialysis is challenging and often inaccurate.<sup>9</sup> In addition, a significant percentage of CKD patients present requiring emergent dialysis treatment.<sup>10</sup>

<sup>1</sup>Department of Vascular Surgery, Institut Mutualiste Montsouris, Paris, France

<sup>2</sup>The University of Texas Medical Branch, Galveston, TX, USA

<sup>3</sup>Department of Vascular Surgery, School of Community Medicine, The University of Oklahoma, Tulsa, OK, USA

### Corresponding author:

William C Jennings, Department of Vascular Surgery, School of Community Medicine, The University of Oklahoma, 1919 S. Wheeling Ave., Ste. 600, Tulsa, OK 74104, USA.  
Email: william-jennings@outlook.com

Not all newly created fistulas become physiologically mature and clinically functional for dialysis access. Failure of maturation has been reported to be as high as 60%.<sup>11</sup> Although not evidence-based, many renal physicians recommend a mandatory waiting period before performing the first cannulation on a physiologically mature AVF based upon the assumption that earlier cannulation will compromise the survival of the access.

Since the introduction of the AVF more than 50 years ago,<sup>12</sup> very little meaningful advance in achieving the goal of having a functional AVF in place ready for use when the need for renal replacement therapy has occurred. In fact, the problem has been exacerbated largely due to changes in the patient population accepted to dialysis programs. Patients are older, three quarters of them have five or more comorbidities, 90% have cardiovascular disease, and 50% are diabetic.<sup>13,14</sup>

The recent advent of the percutaneous arteriovenous fistula (pAVF) may be at least a partial solution of these problems.<sup>15–20</sup> The purpose of this study is report on the results of early cannulation in a group of patients with a newly created pAVF. Can it be done and provide effective hemodialysis and how does this affect access patency?

## Materials and methods

This was a retrospective review of data, which was prospectively collected as part of an electronic medical record. The study was approved by the Institutional Review Board (Comité d'Evaluation des Protocoles et d'Aide à la Recherche, Protocol Evaluation and Research Assistance Committee—CEPAR) and was in accordance with the Declaration of Helsinki. Individual informed consent was not required by the Institutional Review Board since this was a retrospective study. Medical records pertaining to 60 patients in whom a pAVF had been created were queried to identify those patients where early cannulation (defined as cannulation within 14 days of access creation) had been attempted in order to avoid catheter placement either for initiation of dialysis or to replace a problematic catheter in patients already receiving dialysis treatments.

The pAVF procedures were performed at a university-affiliated medical center outpatient department with regional axillary block anesthetic using the Ellipsys® Vascular Access System (Avenu Medical, San Juan Capistrano, Calif). A description of the device used, and the details of the procedure have been previously described.<sup>19,20</sup> In summary, the Ellipsys device consists of a single venous access catheter which is introduced retrograde through cannulation of either the cephalic or median cubital vein at the elbow, advanced through the deep communicating vein (perforating vein), and then into the proximal radial artery. The device uses direct heat and pressure to create a permanent arteriovenous anastomosis by fusion between the deep communicating vein and

adjacent proximal radial artery in the antecubital fossa where these two anatomic structures are adjacent. All procedures were performed with regional anesthesia and conscious sedation under ultrasound guidance. Immediately following the creation of the AVF, the anastomosis and adjacent vein were dilated with a 5 mm angioplasty balloon under ultrasound guidance as a routine part of the primary procedure.

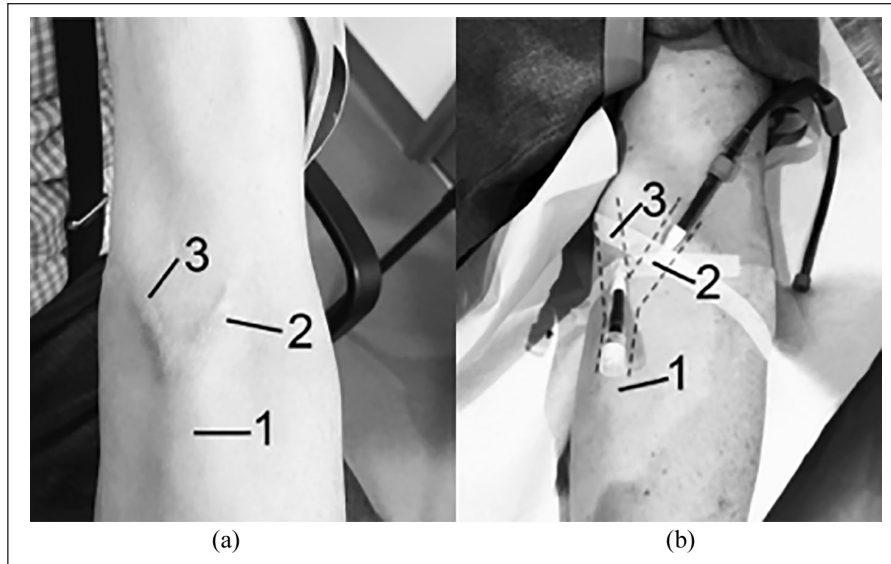
The AVFs created with this technique represent a very homogeneous group that is comparable to the proximal radial artery AVF which has been previously described.<sup>21</sup> Once created, the pAVF drains mainly into the superficial veins of the upper arm (Figure 1). Secondarily, minimal blood flow is present in the brachial vein, which helps maintain low pressures in the entire outflow circuit. All venous outflow branches were evaluated postoperatively and at each follow-up visit using ultrasound imaging and access blood flow volume (Qa) measurements to determine adequacy for dialysis. Qa was determined indirectly by measuring blood flow in the brachial artery, which represented a composite of all draining vessels.<sup>22–24</sup> No patients in the study required venous branch occlusion.

Ultrasound mapping was used to mark cannulation sites for the initial cannulations for each patient. Ultrasound guidance for the first cannulation was used in two patients and was not otherwise required. Plastic (fluorine resin) fistula cannulas (Medikit catheter 16 gauge, 35 mm length; Bernas Medical, Paris, France) were used for early cannulation for all dialysis treatments. Outflow vein diameters of 5–6 mm and depths of 4–5 mm were required for the marked cannulation sites.

All patients were assessed by the dialysis facility staff at each dialysis treatment to determine adequacy of Qa for dialysis and the overall status of the access. In addition, all pAVFs were evaluated postoperatively in the surgery clinic at 1 month and every 3 months thereafter by both physical examination and ultrasound evaluation. Successful cannulation was defined by two-needle access of the pAVF allowing for the completion of the dialysis prescription, thereby avoiding placement of a new catheter or prompt removal of a problematic catheter. Primary, assisted primary, and cumulative patency rates according to standard definitions<sup>25</sup> were determined using Kaplan–Meier life table analysis. Transplantation, lost to follow-up, and patient death were considered to be censored events.

## Results

Fourteen patients met the study requirement of first cannulation within 14 days or less of access creation. These cases formed the basis of this study. Demographic and clinical data on this cohort are presented in Table 1. The age of these patients ranged from 26 to 80 years (mean: 58 years): seven (50%) were female, six (43%) were obese, and seven (50%) were diabetic. Study data are shown in



**Figure 1.** (a) Percutaneous arteriovenous fistula (pAVF) available for early cannulation and (b) pAVF cannulated successfully 5 days after access creation (dashed lines indicate the outflow veins). (1—site of anastomosis, 2—medial cephalic vein, and 3—medial cubital vein).

**Table 1.** Patient demographics.

Number of cases	14
Age (years)	57.8 (range 26–86)
Female	7 (50%)
Diabetes	7 (50%)
Obesity	6 (43%)

Table 2. Immediately post access creation,  $Q_a$  ranged from 491 to 1169 mL/min (mean: 772 mL/min). The time to first cannulation (TFC) ranged from 1 to 12 days with a mean of 8 days. In six cases, TFC was 7 days or less. Ultrasound guidance was used for the initial cannulation in two patients and was not otherwise required. All cannulations were with two needles and with buttonhole technique used most commonly. Nine patients had both cannulation sites in the cephalic vein and five individuals had cannulation with one needle in the median cubital vein and one in the median cephalic vein. The typical dialysis prescription in this cohort of cases consisted of a dialysis blood flow rate of 300 to 350 mL/min, for 4h three times each week. Initiation of sustained clinical use to provide effective dialysis according to the dialysis prescription was successful in all but one case over a follow-up period that ranged from 10 to 17 months (mean: 13 months). Patients were treated according to the attending nephrologist and unit standards that included  $Kt/v$ , recirculation, and arterial and venous pressures.

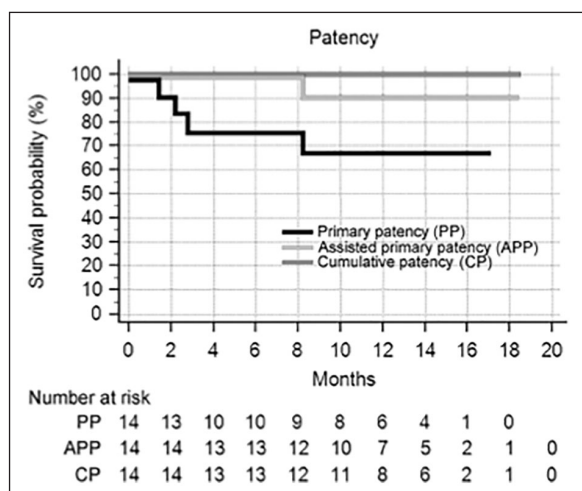
One patient (Case 14), after successful first cannulation, had a cannulation complication that resulted in a hematoma and subsequent cephalic vein occlusion. The pAVF

remained patent with blood flow through the median cubital and brachial veins with plans for a basilic vein staged transposition. Nevertheless, a catheter was required and continued to be used until the patient received a kidney transplant. In all cases, the pAVF remained patent and, except for this single patient, provided effective dialysis according to the dialysis prescription without problems. No other patients experienced cannulation failure. In one case, difficulty was encountered in cannulating the proximal cephalic vein due to its depth. A superficialization procedure was performed enabling the access to be used without further difficulty, and successful cannulation was maintained in an undisturbed segment of the pAVF. In another case, blood flow was lost and investigation revealed occlusion of the anastomosis (anastomotic plug). Blood flow was restored following angioplasty of the anastomosis and the access continued to be used successfully without further problems. In three pAVFs, stenosis occurring in the deep communicating vein required treatment with angioplasty. This was successfully performed, and no further difficulties were encountered in these cases. One individual was lost to follow-up at 8 months and two were transplanted at 2.6 and 12 months, respectively. Two patients died at 8.4 and 12 months from causes unrelated to the procedure. In both instances, the pAVF was functioning without problems immediately prior to the patient's death.

Primary, assisted primary, and cumulative patency rates for the study period are shown in Figure 2. Primary patency at 3, 6, and 12 months was 78%, 78%, and 69%, respectively. Assisted primary patency for the same intervals was 100%, 100%, and 92%, respectively. Cumulative patency was 100% at all three time intervals.

**Table 2.** Study data.

Patient	Initial blood flow (mL/min)	Initial cannulation day (post-operation)	Primary patency (months)	Assisted primary patency (months)	Cumulative patency (months)	Censored event
1	1104	4	8.2	8.2	15.0	Lost to follow-up
2	491	4	11.2	11.2	11.2	
3	760	6	1.4	11.4	11.4	
4	1169	8	2.2	18.4	18.4	
5	572	12	2.8	8.4	8.4	Died
6	1032	5	14.1	14.1	14.1	
7	638	10	8.0	8.0	8.0	
8	866	12	13.6	13.6	13.6	
9	881	7	2.6	2.6	2.6	Transplanted
10	723	8	12.3	12.3	12.3	
11	657	12	14.4	14.4	14.4	
12	638	10	17.1	17.1	17.1	
13	734	1	12.0	12.0	12.0	Died
14	548	10	14.5	14.5	14.5	Transplanted



**Figure 2.** Kaplan–Meier vascular access patency curves show primary, assisted, and cumulative (secondary) patency during the study period. The number of patients at risk for each period are shown. Such an analysis has inherent limitations in studies with smaller numbers of at-risk individuals.

## Discussion

Since the introduction of the AVF more than 50 years ago,<sup>12</sup> very little meaningful advance in achieving the goal of having a functional AVF in place ready for sustained clinical use when the need for renal replacement therapy arrives has occurred. In fact, difficulties in achieving this goal have been exacerbated largely due to changes in the patient population accepted into dialysis programs.<sup>26</sup> Patients are older and three quarters of them have five or more comorbidities, 90% having cardiovascular disease and 50% having diabetes.<sup>13,14</sup>

A clinically functional AVF is the end product of a series of events beginning with the recognition of the

appropriate timing of referral for access creation and ending with the sustained clinical use of the access. Starting with the procedure by which AVF creation is initiated, the AVF evolves through three developmental stages to reach this goal, each one of which is dependent upon the preceding one(s): Stage 1—establishment of a patent AVF (surgical creation and open anastomosis with blood flow), Stage 2—physiological maturation of the AVF, and Stage 3—a clinically functional AVF.<sup>27</sup> Barriers and system failures arise at each stage in this process.

As a result of these problems, many patients start dialysis with a catheter.<sup>28</sup> In the United States, this represented more than 80% of cases in 2016, a percentage unchanged since 2005.<sup>29</sup> Patients experience unnecessary surgery, and early placement of an AVF is at high risk of never being used, especially in older patients.<sup>30–32</sup> Although there is broad agreement on the importance of timely surgical referral for creation of a permanent access, delays in scheduling appointments and procedures are such that the time lapse from surgical referral to a clinically usable AVF can amount to several months.<sup>7,8,33</sup> Many AVFs that are created experience failure to mature, requiring multiple procedures for salvage. Between this and primary surgical failure, over one-third of AVF placements in the United States are lost.<sup>34</sup> Annual costs relating to vascular access is markedly increased because of these problems and can approach US\$100,000.<sup>35</sup> In addition to the discomfort and morbidity associated with multiple surgical procedures, these factors all exert a major adverse effect on the patient's quality of life,<sup>36</sup> a problem the importance of which cannot be overstated.

The current situation related to the standard surgical approach for AVF creation forces the question as to whether a better alternative is available. Preliminary data related to the pAVF suggest that it may, at least in part, provide this alternative. The pAVF possesses all of the

advantages that have been documented for the surgically created proximal radial AVF.<sup>21</sup> In addition, it represents a minimally invasive alternative to open surgical creation of an AVF, which does not require a surgical theater or general anesthesia. The procedure requires substantially less time, personnel, and equipment than a surgical access creation and can be performed in an outpatient facility using local or regional anesthesia and conscious sedation. The pAVF has been shown to have a higher maturation rate, requires fewer post-creation procedures, be more economical, and have a better cumulative patency rate at one year than has been reported for surgically created AVFs.<sup>15–20</sup>

Having access outflow involving both the basilic and cephalic vein allows for easy cannulation of the medial cubital and medial cephalic veins (Figure 1) something not usually possible with a surgically created AVF at this site due to the incision and surgical dissection. The moderate Qa as observed in this study was typical of proximal radial artery inflow AVFs and was adequate to fulfill the needs of the dialysis prescription in these patients (300 to 350 mL/min). Moderate blood flow also offers the possible advantages of a decreased incidence of congestive heart failure, dialysis access steal syndrome, and neointimal hyperplasia associated with the turbulence of high blood flow.<sup>21</sup>

This study has certain limitations over and beyond those inherent to observational studies. The major limitation is the size of the cohort studied. The question as to the success of early cannulation using a higher Qa remains unanswered. The plastic cannulation needles which contributed to the early success in this study may not be available in all dialysis facilities and are not yet available in the United States. While success with early cannulation in this small series of cases suggests that the pAVF could serve as an alternative to a catheter for immediate dialysis use, a larger study is needed in order to confirm these findings.

## Conclusion

Data derived from this study suggest that early cannulation, as early as day 1, is feasible with the pAVF allowing for the avoidance of a central venous catheter. Ultrasound mapping of potential cannulation sites and ultrasound-guided cannulation in selected cases played an important role in the success of this study.<sup>37,38</sup> The use of plastic needles was also felt to contribute to the success of early cannulation<sup>39,40</sup> although not felt to be necessary in all patients, especially after the initial month of access use.




## Declaration of conflicting interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: A.M.: Avenu Medical consultant/stock option; G.A.B.: none; W.C.J.: Avenu Medical consultant/stock option.

## Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

## ORCID iDs

Alexandros Mallios  <https://orcid.org/0000-0003-0641-6050>  
 Gerald A Beathard  <https://orcid.org/0000-0002-0698-9329>  
 William C Jennings  <https://orcid.org/0000-0003-3599-0609>

## References

1. Dhingra RK, Young EW, Hulbert-Shearon TE, et al. Type of vascular access and mortality in U.S. hemodialysis patients. *Kidney Int* 2001; 60(4): 1443–1451.
2. Polkinghorne KR, McDonald SP, Atkins RC, et al. Vascular access and all-cause mortality: a propensity score analysis. *J Am Soc Nephrol* 2004; 15(2): 477–486.
3. Di Iorio BR, Bellizzi V, Cillo N, et al. Vascular access for hemodialysis: the impact on morbidity and mortality. *J Nephrol* 2004; 17(1): 19–25.
4. Ozeki T, Shimizu H, Fujita Y, et al. The type of vascular access and the incidence of mortality in Japanese dialysis patients. *Intern Med* 2017; 56(5): 481–485.
5. Murad MH, Elamin MB, Sidawy AN, et al. Autogenous versus prosthetic vascular access for hemodialysis: a systematic review and meta-analysis. *J Vasc Surg* 2008; 48(5 Suppl.): 34S–47S.
6. NKF-K/DOQI. Clinical practice guidelines for hemodialysis adequacy, update 2006. *Am J Kidney Dis* 2006; 48(Suppl. 1): S2–S90.
7. Lee T, Barker J and Allon M. Tunneled catheters in hemodialysis patients: reasons and subsequent outcomes. *Am J Kidney Dis* 2005; 46(3): 501–508.
8. Ethier J, Mendelssohn DC, Elder SJ, et al. Vascular access use and outcomes: an international perspective from the Dialysis Outcomes and Practice Patterns Study. *Nephrol Dial Transplant* 2008; 23(10): 3219–3226.
9. O'Hare AM, Allon M and Kaufman JS. Whether and when to refer patients for predialysis AV fistula creation: complex decision making in the face of uncertainty. *Semin Dial* 2010; 23(5): 452–455.
10. Molnar AO, Hiremath S, Brown PA, et al. Risk factors for unplanned and crash dialysis starts: a protocol for a systematic review and meta-analysis. *Syst Rev* 2016; 5(1): 117.
11. Oliver MJ. The science of fistula maturation. *J Am Soc Nephrol* 2018; 29(11): 2607–2609.
12. Brescia MJ, Cimino JE, Appel K, et al. Chronic hemodialysis using venipuncture and a surgically created arteriovenous fistula. *N Engl J Med* 1966; 275: 1089–1092.
13. Mendelssohn DC, Ethier J, Elder SJ, et al. Haemodialysis vascular access problems in Canada: results from the Dialysis Outcomes and Practice Patterns Study (DOPPS II). *Nephrol Dial Transplant* 2006; 21(3): 721–728.
14. Woods JD, Turenne MN, Strawderman RL, et al. Vascular access survival among incident hemodialysis patients in the United States. *Am J Kidney Dis* 1997; 30(1): 50–57.
15. Rajan DK and Lok CE. Promises for the future: minimally invasive fistula creation. *J Vasc Access* 2015; 16(Suppl. 9): S40–S41.

16. Rajan DK, Ebner A, Desai SB, et al. Percutaneous creation of an arteriovenous fistula for hemodialysis access. *J Vasc Interv Radiol* 2015; 26: 484–490.
17. Lok CE, Rajan DK, Clement J, et al. Endovascular proximal forearm arteriovenous fistula for hemodialysis access: results of the prospective, multicenter Novel Endovascular Access Trial (NEAT). *Am J Kidney Dis* 2017; 70(4): 486–497.
18. Yang S, Lok C, Arnold R, et al. Comparison of post-creation procedures and costs between surgical and an endovascular approach to arteriovenous fistula creation. *J Vasc Access* 2017; 18(Suppl. 2): 8–14.
19. Hull JE, Jennings WC, Cooper RI, et al. The pivotal multicenter trial of ultrasound-guided percutaneous arteriovenous fistula creation for hemodialysis access. *J Vasc Interv Radiol* 2018; 29(2): 149.e5–158.e5.
20. Mallios A, Jennings WC, Boura B, et al. Early results of percutaneous arteriovenous fistula creation with the Ellipsys Vascular Access System. *J Vasc Surg* 2018; 68(4): 1150–1156.
21. Jennings WC, Mallios A and Mushtaq N. Proximal radial artery arteriovenous fistula for hemodialysis vascular access. *J Vasc Surg* 2018; 67(1): 244–253.
22. Wiese P and Nonnast-Daniel B. Colour Doppler ultrasound in dialysis access. *Nephrol Dial Transplant* 2004; 19(8): 1956–1963.
23. Chowdhury S, Goss D, Mistry H, et al. Duplex ultrasound volumetric flow analysis before and after hemodialysis in patients with brachio-cephalic fistulae. *J Vasc Access* 2013; 14(4): 342–347.
24. Ferring M, Henderson J and Wilmlink T. Accuracy of early postoperative clinical and ultrasound examination of arteriovenous fistulae to predict dialysis use. *J Vasc Access* 2014; 15(4): 291–297.
25. Shenoy S, Allon M, Beathard G, et al. Clinical trial end points for hemodialysis vascular access: background, rationale, and definitions. *Clin J Am Soc Nephrol* 2018; 13(3): 490–494.
26. Allon M and Robbin ML. Increasing arteriovenous fistulas in hemodialysis patients: problems and solutions. *Kidney Int* 2002; 62(4): 1109–1124.
27. Beathard GA, Lok CE, Glickman MH, et al. Definitions and end points for interventional studies for arteriovenous dialysis access. *Clin J Am Soc Nephrol* 2018; 13(3): 501–512.
28. Pisoni RL, Zepel L, Port FK, et al. Trends in US vascular access use, patient preferences, and related practices: an update from the US DOPPS practice monitor with international comparisons. *Am J Kidney Dis* 2015; 65(6): 905–915.
29. USRDS. Annual data report, 2018, <https://www.usrds.org/adr.aspx>
30. O'Hare AM, Bertenthal D, Walter LC, et al. When to refer patients with chronic kidney disease for vascular access surgery: should age be a consideration? *Kidney Int* 2007; 71(6): 555–561.
31. Shechter SM, Skandari MR and Zalunardo N. Timing of arteriovenous fistula creation in patients With CKD: a decision analysis. *Am J Kidney Dis* 2014; 63(1): 95–103.
32. Oliver MJ, Quinn RR, Garg AX, et al. Likelihood of starting dialysis after incident fistula creation. *Clin J Am Soc Nephrol* 2012; 7(3): 466–471.
33. Goel N, Kwon C, Zachariah TP, et al. Vascular access placement in patients with chronic kidney disease Stages 4 and 5 attending an inner city nephrology clinic: a cohort study and survey of providers. *BMC Nephrol* 2017; 18(1): 28.
34. Beecher BA, Taubman KE and Jennings WC. Simple and durable resolution of steal syndrome by conversion of brachial artery arteriovenous fistulas to proximal radial artery inflow. *J Vasc Access* 2010; 11(4): 352–355.
35. Thamer M, Lee TC, Wasse H, et al. Medicare costs associated with arteriovenous fistulas among US hemodialysis patients. *Am J Kidney Dis* 2018; 72(1): 10–18.
36. Lok CE, Sontrop JM, Tomlinson G, et al. Cumulative patency of contemporary fistulas versus grafts (2000–2010). *Clin J Am Soc Nephrol* 2013; 8(5): 810–818.
37. Ward F, Faratro R and McQuillan RF. Ultrasound-guided cannulation of the hemodialysis arteriovenous access. *Semin Dial* 2017; 30(4): 319–325.
38. Luehr A. Use of ultrasound guidance during cannulation of arteriovenous fistulas. *Nephrol Nurs J* 2018; 45(5): 423–434.
39. Letachowicz K, Kusztal M, Golebiowski T, et al. Use of plastic needles for early arteriovenous fistula cannulation. *Blood Purif* 2015; 40(2): 155–159.
40. Nalesso F, Garzotto F, Muraro E, et al. Fistula cannulation with a novel fistula cannula: a review of cannulation devices and procedures. *Blood Purif* 2018; 45(1–3): 278–283.